

# Food and Drug Administration Office of Regulatory Affairs Collection Report

## For Sample: 2340

<b>Flag</b>		<b>Flag Remarks</b>			
301 (k) Sample					
<b>Episode Number</b>	<b>Origin</b>	<b>Basis</b>	<b>Sample Type</b>	<b>FIS Smpl Num</b>	<b>Status</b>
Progress	Domestic	Compliance	Documentary	00908358	In
<b>FEI</b>	<b>Date Collected</b>	<b>Product Code</b>	<b>Responsible Firm</b>	<b>PAC</b>	<b>Hours</b>
3000901032	09/25/2000	60LBA05	Dealer	56002	8
<b>Related Smpl Num Rqrmnt.</b>	<b>Position Class</b>	<b>Sampling District</b>	<b>NDC Number</b>	<b>Permit Number</b>	<b>Storage</b>
	2	CHI-DO			
<b>Dealer is Consumer</b>	<b>Crx/DEA Schedule</b>	<b>Recall Num</b>	<b>Consumer Compl. Num</b>	<b>Brand Name</b>	
No				Wilaprin Arthritis Formula	
<b>Product Description</b>					
Aspirin Non-Rx Combination Tablet					
<b>Product Label</b>					
See continuation					
<b>Reason for Collection</b>			<b>MFG Codes</b>	<b>Expiration Date</b>	
Collected during EI of dealer, dated 9/20-25/2000 to document Interstate commerce and cGMP deviations. No analysis needed			"Lot 25C83" (Finished Product)	8/06	
			"Batch 5564"(Active Ingredient)	8/02	
<b>Firm Legal Name</b>	<b>Address</b>		<b>Type of Firm</b>	<b>Firm FEI</b>	<b>FCE</b>
Wilson Pharmaceutical	300 Riverside Chicago, IL 60606 US		Dealer	3000901032	
Woleske Chemical	100 W. Main Kansas City, MO 64111 US		Ingredient	3000901033	
			Supplier		
<b>Size of Lot</b>	<b>Est. Value</b>	<b>Rcpt Type</b>	<b>Date Shipped &amp; Doc. Ref.</b>		
125 CS/12 BTLS/100 TAB	\$4,500	None	06/06/1999		
<b>Description of Sample</b>					
Sample consists of photographs and copies of records documenting interstate commerce and cGMP deficiencies for Wilaprin Arthritis Formula					
<b>Method of Collection</b>					
Copies of records collected during EI, dated 09/20-25/2000. Photographs taken 09/23/2000.					
<b>How Prepared</b>					
See continuation.					
<b>Collector's Identification on Package and/or Label</b>			<b>Collector's Identification on Seal</b>		
"DOC 2340 9/25/00 SHR"			"DOC 2340 9/25/00 Sylvia H. Rogers"		
<b>Sample Delivered To</b>	<b>Date Delivered</b>		<b>Orig C/R &amp; Records To</b>		
			CH-DO		
	<b>Lab w/Split Sample</b>		<b>Lab</b>		
<b>Document Number</b>	<b>Document Date</b>	<b>Document Type</b>	<b>Document Remarks</b>		
1	09/25/2000	Affidavit	Affidavit signed by Robert Wilson, President		
2	06/16/199	Invoice	Invoice no. 2346 dated 06/16/2000 from Woleske Chemical, Kansas, MO for 1 -250 lb drum of Acetylsalicylic Acid, batch 5564		
3	06/16/2000	Bill of Lading	Bill of Lading no. 124679 dated 06/16/2000 from Roadway, Inc. Smith Center Kansas for shipment of		
<b>Date:</b> 10/14/2000			<b>Page:</b> 1 of 3		

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4	Other	250 lbs of Acetylsalicylic Acid from Woleske Chemical, Kansas City, MO to Wilson Pharmaceutical, Inc. Chicago, IL.
5	Other	Raw Material Inventory Card for Acetylsalicylic Acid Batch no 5564
6	Other	Photographs of labeling for bulk 250 lb. Drum of Acetylsalicylic Acid, Batch 5564
		Wilson Pharmaceuticals Batch Record for Wilaprin Arthritis Formula, lot 25C83-25 pages. (contains Copies of all labeling distributed with lot 25C83)

### Remarks

See EIR of dealer and FDA-483, dated 9/20/25/2000 for more information. FDA-483 points 1-12 discuss deviations specific to this product.

<b>Payment Amount</b>	<b>Payment Method</b>	<b>704(d) Sample</b>	<b>702(b) Portion</b>	<b>Collector's</b>
<b>Name</b>				
\$0.00	No Charge	No	Silvia H. Rogers	
<b>Name of Signer</b>		<b>Date &amp; Time of Signature</b>		<b>Meaning</b>
		ET		

**Food and Drug Administration Office of Regulatory Affairs  
Collection Report****For Sample: 2340****Continuation:****Product Label**

Finished product is labeled in part: "\*\*\*\*WILLAPRIN ARTHRITIS FORMULA 500 Tablets\*\*\*Active Ingredients: Acetylsalicylic Acid...500 mg, Caffeine...32 mg.\*\*\* 100 Tablets\*\*\* Lot 25C83\*\*\* EXP 8/06\*\*\*Wilson Pharmaceuticals, Chicago, IL 60606\*\*\*". 12 bottles are placed in a case, labeled in part: "\*\*\*\*WILLAPRIN ARTHRITIS FORMULA\*\*\*Wilson Pharmaceuticals\*\*\*Lot 25C83\*\*\*EXP 8/06\*\*\*"

Active ingredient documented is Acetylsalicylic Acid packaged in 250 lb drum, labeled in part:"\*\*\*Acetylsalicylic Acid, USP\*\*\*Batch No 5564\*\*\*Use by 8/02\*\*Woleske Chemical, Kansas City, MO 64111\*\*\*\*"

**How Prepared**

All records and photographs identified as below and submitted to Supervisory Investigator. Negatives and extra photos placed in 525, sealed as below and submitted to Supervisor.